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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,998	04/12/2002	David N. Armstrong	10148-1020	6172

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EXAMINER

MENDOZA, MICHAEL G

ART UNIT                      PAPER NUMBER

3731

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/042,998	<b>Applicant(s)</b> ARMSTRONG, DAVID N.	
	<b>Examiner</b> Michael G. Mendoza	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 03 May 2005.
- 2a)  This action is **FINAL**.                      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 26-35, 55, 57-62, 64, 66-73 and 75-77 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) 26-35, 55, 57-62, 64 and 77 is/are allowed.
- 6)  Claim(s) 66-68 and 71-73 is/are rejected.
- 7)  Claim(s) 69, 70, 75 and 76 is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:
1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments, see pgs 12 and 13, filed 3 May 2005, with respect to claims 26, 55, and 77 have been fully considered and are persuasive. The U.S.C. 103(a) rejections of claims 26-35, 55, 57-62, 64, and 77 have been withdrawn.
2. Applicant's arguments filed 3 May 2005 have been fully considered but they are not persuasive. As to claim 66, the Applicant argues that Bayer does not disclose or suggest the apertures being formed at a predetermined sized, and visual means at the proximal end of the of the cylinder. Bayer does teach that the apertures are of a predetermined size. The size is determined by the spacing of the stips 22 of the device (col. 3, lines 1-7). Bayer teaches a visual means 24. Furthermore, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 66-68, 71-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watson Jr. et al. 5788715 in view of Bayer 6126594 in further view of Bidoia 5203863.

5. Watson teaches a system for ligation of internal hemorrhoids comprising a ligator device configured to store multiple bands on a cylinder and further configured to release a single rubber band at a time from the cylinder. No anoscope or loading cone is disclosed by Watson. Bayer teaches an anoscope with a hollow cylinder with multiple apertures formed about the hollow cylinder at positions about the hollow cylinder for simultaneously exposing hemorrhoids in the anal canal (col. 1, lines 63-64; see figure). To perform a hemorrhoid surgery it is well known in the art to use an anoscope to allow the ligation tool to enter the anus. Bayer describes instruments can be disposed through the anoscope to access any number of hemorrhoids (col. 1, lines 56-67). At the time of the invention it would have been obvious to one having ordinary skill in the art to combine the Watson device with the anoscope of Bayer because Bayer teaches that hemorrhoid surgery is performed by using a ligating instrument and an anoscope. The combined device does not disclose a reloading mechanism for placing rubber bands onto the Watson device in the event additional bands are needed, or if the surgery is repeated. Bidoia discloses a loading mechanism that allow multiple rubber bands to be placed on the inner cylinder of the Watson device. At the time of the invention it would have been obvious to one having ordinary skill in the art to use the Bidoia loading cone to load the Watson ligator for allowing bands to be replace onto the device.

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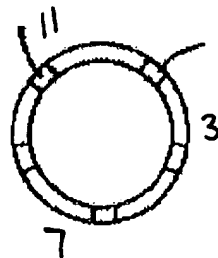
6. Regarding claim 66, Bayer teaches a cylinder having a distal end for insertion in the anal canal and a proximal end for positioning exteriorly of the anal canal, the cylinder defining three lateral apertures opening from the distal end of the cylinder toward the proximal end of the cylinder, the apertures being spaced apart about the cylinder to be positionable at the three o'clock, seven o'clock and eleven o'clock positions about the cylinder, the apertures being formed at a predetermined sized; and visual means 24.

7. Regarding claims 67 the Bayer anoscope wherein the visual means comprises a handle 24.

8. Regarding claims 68, Bayer fails to specifically teach wherein the cylinder is tapered. However, it is well known in the art of anosscopes to use a tapered design to aid insertion into the anus. Therefore it would have been obvious to one having ordinary skill in the art to taper the cylinder of Bayer to make the insertion of the anoscope easier.

9. Regarding claims 71 and 72 the anoscope of Bayer comprises: a flange extending radially from the proximal end of the cylinder and a handle extending from the flange.

10. Regarding claims 73, Bayer discloses an optic fiber or light can be part of the anoscope (col. 3, lines 20-27).



***Allowable Subject Matter***

11. Claims 26-35, 55, 57-62, 64, and 77 are allowable over the prior art of record.

12. Claims 69, 70, 75, and 76 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fails to teach or render obvious the overall claimed invention of a system for ligation of internal hemorrhoids in the anal canal with the hemorrhoids at the traditional anatomical positions of the hemorrhoids in the human body, comprising: an anoscope, a multiple rubber band ligator device and a loading cone device, the anoscope is configured with an elongate cylinder with three apertures from about the cylinder and extending from a distal end along approximately one-half the length of the cylinder; or wherein the apertures each being one-sixth of the circumference of the cylinder.

***Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-44963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MM



GLENN K. DAWSON  
PRIMARY EXAMINER